Supreme Court, U.S.
FILED
MAR 31 1989
JOSEPH F. SPANIOL, JR.
CLERK

No. 88-1146

In the Supreme Court of the United States

OCTOBER TERM, 1988

RALPH NADER, ET AL., PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

WILLIAM C. BRYSON
Acting Solicitor General
DONALD A. CARR
Acting Assistant Attorney General
ASHLEY DOHERTY
Attorney

Department of Justice
Washington, D.C. 20530
(202) 633-2217

QUESTIONS PRESENTED

1. Whether the federal courts of appeals have jurisdiction under Section 408(i) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(i), to review a refusal by the Environmental Protection Agency to propose regulations that would eliminate tolerances for a pesticide applicable to raw agricultural commodities.

2. Whether, under Section 409(g) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 348(g), a party may obtain judicial review of the Environmental Protection Agency's denial of a petition proposing the elimination of tolerances for a pesticide applicable to processed foods, without first filing objections to the denial of the petition in accordance with Section 408(f) of the Act, 21 U.S.C. 348(f).

TABLE OF CONTENTS

	Page
Opinion below	1
Jurisdiction	1
Statement	1
Argument	11
Conclusion	23

TABLE OF AUTHORITIES

Cases:

Commonwealth Edison Co. v. *Nuclear Regulatory Comm'n*, 830 F.2d 610 (7th Cir. 1987)	17
Community Nutrition Inst. v. *Young*, 773 F.2d 1356 (D.C. Cir. 1985), cert. denied, 475 U.S. 1123 (1986)	21
Cutler v. *Hayes*, 818 F.2d 879 (D.C. Cir. 1987)	12
Environmental Defense Fund v. *HEW*, 428 F.2d 1083 (D.C. Cir. 1970)	17
Florida Power & Light Co. v. *Lorion*, 470 U.S. 729 (D.C. Cir. 1985)	11, 12, 15, 16
Modine Mfg. Corp. v. *Kay*, 791 F.2d 267 (3d Cir. 1986)	17
National Coalition Against the Misuse of Pesticides v. *Thomas*, 809 F.2d 875 (D.C. Cir. 1987)	20
Public Citizen v. *Bowen*, 833 F.2d 364 (D.C. Cir. 1987)	20
Public Utility Comm'r v. *Bonneville Power Admin.*, 767 F.2d 622 (9th Cir. 1985)	17
Telecommunications Research & Action Center v. *FCC*, 750 F.2d 70 (D.C. Cir. 1984)	17
Tennessee v. *Herrington*, 806 F.2d 642 (6th Cir.), cert. denied, 107 S. Ct. 1604 (1987)	17
Vineland Chemical Co. v. *EPA*, 810 F.2d 402 (3d Cir. 1987)	17

Statutes and regulations:

Administrative Procedure Act:	
5 U.S.C. 551(6)	10, 13
5 U.S.C. 551(13)	14
5 U.S.C. 701(a)	15
5 U.S.C. 706(2)(A)	16

Statutes and regulations—Continued: Page

Atomic Energy Act of 1954, § 189, 42 U.S.C. 2239 12
Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 *et seq.*:
§ 402(a)(2), 21 U.S.C. 342(a)(2)(C) 5
§ 402(a), 21 U.S.C. 342(a) 3
§ 408, 21 U.S.C. 346a ..... *passim*
§ 408(a), 21 U.S.C. 346a(a) 3
§ 408(e), 21 U.S.C. 346(e) 20
§ 408(b), 21 U.S.C. 346a(b) 2, 3, 20
§ 408(d), 21 U.S.C. 346a(d) 3, 17
§ 408(d)(1), 21 U.S.C. 346a(d)(1) 3
§ 408(d)(2)-(3), 21 U.S.C. 346a(d)(2)-(3) 3
§ 408(d)(5), 21 U.S.C. 346a(d)(5) 4, 20
§ 408(e), 21 U.S.C. 346a(e) 4, 10, 13, 14, 20
§ 408(i), 21 U.S.C. 346a(i) (1982 & Supp. IV 1986) .. 2, 9, 15
§ 408(i)(1), 21 U.S.C. 346a(i)(1) 4, 13
§ 408(m), 21 U.S.C. 346a(m) 4
§ 409, 21 U.S.C. 348 ..... *passim*
§ 409(a)(2)(C), 21 U.S.C. 348(a)(2)(C) 5
§ 409(b), 21 U.S.C. 348(b) 5
§ 409(c), 21 U.S.C. 348(c) 18, 19
§ 409(c)(1), 21 U.S.C. 348(c)(1) 6
§ 409(c)(1)(B), 21 U.S.C. 348(c)(1)(B) 14
§ 409(c)(3), 21 U.S.C. 348(c)(3) 5
§ 409(d), 21 U.S.C. 348(d) 6, 13, 19
§ 409(d)(1), 21 U.S.C. 348(d)(1) 21
§ 409(f), 21 U.S.C. 348(f) 19, 21
§ 409(f)(1), 21 U.S.C. 348(f)(1) 6
§ 409(f)(2), 21 U.S.C. 348(f)(2) 6, 19
§ 409(g), 21 U.S.C. 348(g) (1982 & Supp. IV 1986) ... 2, 6, 9, 11, 19
§ 409(g)(1), 21 U.S.C. 348(g)(1) 6
§ 505, 21 U.S.C. 355 (1982 & Supp. IV 1986) 14
§ 512, 21 U.S.C. 360b 14
§ 706, 21 U.S.C. 376 14
Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.* 3
7 U.S.C. 136-136y .....
7 U.S.C. 136d(b) 8
7 U.S.C. 136w(d) 8

Statutes and regulations – Continued: Page

Hobbs Act, 28 U.S.C. 2341 *et seq.* 12, 17
28 U.S.C. 2342(1) 17
28 U.S.C. 1331 15
28 U.S.C. 1631 18
47 U.S.C. 402(a) 17
Reorg. Plan No. 3 of 1970, 5 U.S.C. App. 1132-1134 (1982) 2
21 C.F.R. 193.410 (1985) 7
40 C.F.R.:
Section 180.29 13
Section 180.246 (1985) 7

Miscellaneous:

49 Fed. Reg. 29,136 (1984) 7
51 Fed. Reg. 12,889 (1986) 8
52 Fed. Reg. (1987):
p. 1,909 8
p. 6,348 22
p. 27,543 22
p. 27,256 8
54 Fed. Reg. 6,392 (Feb. 10, 1989) 8
S. Rep. No. 1635, 83d Cong., 2d Sess. (1954) 14
S. Rep. No. 2422, 85th Cong., 2d Sess. (1958) 19

In the Supreme Court of the United States

OCTOBER TERM, 1988

No. 88-1146

RALPH NADER, ET AL., PETITIONERS

v.

ENVIRONMENTAL PROTECTION AGENCY, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

OPINION BELOW

The opinion of the court of appeals (Pet. App. 1-19) is reported at 859 F.2d 747.

JURISDICTION

The judgment of the court of appeals was entered on October 14, 1988. The petition for a writ of certiorari was filed on January 11, 1989. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

Petitioners seek judicial review of the Environmental Protection Agency's (EPA) denial of an administrative petition that sought revocation of tolerances for the pesti-

cide Alar applicable to both raw agricultural commodities and processed foods. The court of appeals held that it lacked jurisdiction to review that action under Sections 408(i) and 409(g) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 346a(i), 348(g) (1982 & Supp. IV 1986).

1. Sections 408 and 409 of the Act empower the EPA to promulgate regulations setting tolerances—permissible amounts, expressed in terms of parts per million—for pesticide residues in or on raw agricultural commodities and processed foods.[1] Section 408 applies to raw agricultural commodities, but tolerances established in accordance with its terms "carry over" to processed foods made from such commodities. That is, processed foods made from a raw agricultural product may be marketed if they contain no more of a pesticide than is permitted by the Section 408 tolerance for that raw product. However, before a processed food containing a pesticide in an amount in excess of a Section 408 tolerance can be marketed, a separate tolerance for that food must be promulgated under Section 409. Though similar safety issues arise under Sections 408 and 409, they were enacted separately, and their procedural provisions differ, with respect both to the promulgation of regulations setting tolerances and judicial review.

a. Section 408 authorizes the EPA to promulgate "regulations establishing tolerances with respect to the use in or on raw agricultural commodities" of pesticides "to the extent necessary to protect the public health." 21 U.S.C. 346a(b). The statute specifies some of the factors that the Agency is to consider in determining how to pro-

[1] Under the 1970 Reorganization Plan through which the EPA was established, the authority to set tolerances for pesticide chemicals under 21 U.S.C. 346a and 348 was transferred to the EPA. Reorg. Plan No. 3 of 1970, 5 U.S.C. App. 1132-1134 (1982).

tect the public health,[2] and authorizes the Administrator to establish the tolerance for a pesticide at zero "if the scientific data before the Administrator does [sic] not justify the establishment of a greater tolerance." *Ibid.* If a pesticide not generally recognized as safe is present on a raw agricultural commodity, and either no tolerance has been set for that pesticide or the amount of the pesticide exceeds the tolerance, the commodity is considered "adulterated" under the FDCA and is subject to various enforcement provisions whose purpose is to keep the commodity off the market. 21 U.S.C. 342(a), 346a(a).

Under Section 408, a rulemaking to establish a tolerance may be initiated only by specified private parties or the EPA. Section 408(d) allows "[a]ny person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA]," 7 U.S.C. 136 *et seq.*,[3] to propose a regulation establishing a tolerance under Section 408. 21 U.S.C. 346a(d)(1). When such a petition is filed, the EPA is obligated to publish a regulation "by order" either "(A) establishing a tolerance for the pesticide chemical * * * or (B) exempting the pesticide chemical from the necessity of a tolerance * * *." 21 U.S.C. 346a(d)(2)-(3). Within 30 days of the publication

---

[2] Section 408(b), 21 U.S.C. 346a(b), provides in pertinent part:

> In establishing any such regulation, the Administrator shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion submitted with a certification of usefulness under subsection (*l*) of this section.

[3] Under this Act, the EPA regulates the registration, sale, and distribution of pesticides.

of the regulation, "any person adversely affected by" the regulation may file objections with the Agency. After conducting further specified proceedings, the EPA acts on the objections and "by order" issues a regulation, either adhering to or modifying the earlier regulation. Such orders must be based "on substantial evidence of record at [a] hearing," and must be accompanied by "detailed findings of fact upon which the regulation is based." 21 U.S.C. 346a(d)(5).

Under Section 408(e), 21 U:S.C. 346a(e), the Administrator of the EPA "may at any time, upon his own initiative or upon the request of any interested person," propose a regulation establishing a tolerance. When it exercises its discretion under this subsection, the EPA first publishes a proposal and thereafter "by order publish[es] a regulation based upon the proposal." *Ibid.* Regulations issued in this manner are subject to the same procedures for objections and detailed factfinding on the record that apply to regulations based on a petition filed by a FIFRA registrant. *Ibid.* Rulemakings to amend tolerances are governed by the same procedures as those that apply to the promulgation of tolerances. 21 U.S.C. 346a(m).

Section 408(i)(1), 21 U.S.C. 346a(i)(1), allows "any person who will be adversely affected" by an "order" issued under subsection (d)(5) or (e) to obtain judicial review in the courts of appeals:

> In a case of actual controversy as to the validity of any order under subsections (d)(5), (e), or (*l*) of this section any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days

after the entry of such order, a petition praying that the order be set aside in whole or in part.

b. Section 409 of the Act, 21 U.S.C. 348, authorizes the EPA to promulgate regulations prescribing tolerances for pesticides in processed foods.[4] The EPA may not issue such a regulation if "a fair evaluation of the data before [it] fails to establish that the proposed use of the [pesticide], under the conditions of use to be specified in the regulation, will be safe." 21 U.S.C. 348(c)(3). In addition, under the "Delaney Clause" of Section 409, a pesticide may not be found to be safe "if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal." 21 U.S.C. 348(c)(3).

Section 409(b), 21 U.S.C. 348(b), allows "[a]ny person" to file "a petition proposing the issuance of a regulation prescribing the conditions under which" a pesticide may be safely used in a processed food. After conducting specified proceedings on such a proposal, the EPA must "(A) by order establish a regulation (whether or not in accord with

---

[4] In general, Section 409 applies to any "food additive" in any food. However, pesticides in or on a raw agricultural commodity are excluded from the definition of "food additives" and, when pesticide residues remain in processed food in an amount lower than the Section 408 tolerance prescribed for the raw commodity from which that food is made, the food is not considered "adulterated" under the FDCA. 21 U.S.C. 342(a)(2)(C), 348(a). In effect, therefore, Section 409 applies to pesticide residues in processed food only when no Section 408 tolerance has been established or the pesticide residues in the food exceed the tolerance fixed under Section 408 for the relevant raw commodity. The latter situation occurs when the effect of processing a commodity is to concentrate a pesticide.

The Food and Drug Administration administers Section 409 with respect to all additives other than pesticides.

that proposed by the petitioner) prescribing, with respect to one or more of the proposed uses of the [pesticide] involved, the conditions under which such [pesticide] may be safely used * * * " or "(B) by order deny the petition * * *." 21 U.S.C. 348(c)(1).[5]

When the EPA has issued an order that establishes a tolerance for a pesticide, whether in response to a petition or on the Agency's initiative, or has denied a petition proposing such a regulation, "any person adversely affected by such an order may file objections * * *." 21 U.S.C. 348(f)(1). After conducting proceedings prescribed by Section 409(f), the EPA must "by order act upon such objections" (21 U.S.C. 348(f)(1)). Its order must be "based upon a fair evaluation of the entire record at [a] hearing" and must include "a statement setting forth in detail the findings and conclusions upon which the order is based" (21 U.S.C. 348(f)(2)).

"[A]ny person who will be adversely affected by" an order issued under subsection (f) may seek judicial review of that order. 21 U.S.C. 348(g). Section 409, however, does not provide for judicial review of orders issued under subsections governing earlier stages of the rulemaking. Section 409(g)(1), 21 U.S.C. 348(g)(1), provides:

> In a case of actual controversy as to the validity of any order issued under subsection (f) of this section, including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the

---

[5] Under Section 409(d), the EPA may "at any time, upon [its] own initiative, propose the issuance of a regulation" establishing a pesticide tolerance under Section 409. 21 U.S.C. 348(d). After such a proposal has been published, the Administrator "may by order establish a regulation based upon the proposal." *Ibid.*

United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after entry of such order, a petition praying that the order be set aside in whole or in part.

2. Daminozide is a plant growth regulator sold by respondent Uniroyal Chemical Company under the tradename "Alar." First registered under FIFRA in 1963, Alar was approved for use on apples (its principal use) in 1968. Alar is used to prevent apples from dropping off trees prior to harvest, to enhance the apples' size and color, and to prevent spoiling. See Pet. App. 6. Prior to 1986, the existing tolerances for daminozide in raw products were set at 30 parts per million ("ppm") or higher, and for certain processed foods (*i.e.*, tomatoes and dried prunes) at up to 320 ppm. 40 C.F.R. 180.246 (1985); 21 C.F.R. 193.410 (1985).

Beginning in 1973, the EPA received several studies suggesting that daminozide (or its component known as unsymmetrical dimethylhydrazine or UDMH) caused cancer in animals (Pet. App. 6-7, 48). Accordingly, in 1984, the EPA initiated a special review to determine whether to cancel Alar's FIFRA registration. 49 Fed. Reg. 29,136 (1984). During that review, Uniroyal, the sole registrant of daminozide, submitted comments criticizing the validity and relevance of the studies that suggested that daminozide was carcinogenic (Pet. App. 7). After considering the available information, the EPA prepared a draft position document concluding that daminozide and UDMH presented a dietary cancer risk, and that children were exposed to a larger risk than adults (*id.* at 7-8, 51-52). On this basis, as well as an estimate of the benefits of daminozide, the draft proposed the cancellation of all

food uses of daminozide. It concluded that no measure short of cancellation would reduce dietary risks to a point where they would be outweighed by that pesticide's benefits. *Id.* at 52.

As required by FIFRA, 7 U.S.C. 136w(d), EPA submitted its proposed decision to an outside Science Advisory Panel composed of seven scientists nominated by the National Institutes of Health and the National Science Foundation. After a hearing, the Panel concluded, on October 4, 1985, that, while the existing studies raised concerns, the available data were inadequate to perform a qualitative assessment of the risk of Alar (Pet. App. 8, 52). The panel criticized the manner in which the EPA had performed the quantitative risk assessments in the draft position document, stating that it had reservations concerning the technical soundness of those assessments. *Id.* at 8. The Department of Agriculture, to which the draft had been referred under 7 U.S.C. 136d(b), also reported to the EPA its view that the draft study underestimated the benefits of daminozide. Pet. App. 8.

After considering the views of the Scientific Advisory Panel, the Agriculture Department's comments, and other available information, the EPA announced on January 22, 1986, that it would not issue a notice of intent to cancel daminozide's registration. It reserved final decision on the registration until reliable data were obtained and directed Uniroyal to conduct studies on daminozide and UDMH. There was no challenge to the decision not to cancel daminozide's FIFRA registration. Pet. App. 8-9, 52.[6]

---

[6] In addition to requiring Uniroyal to conduct additional studies, the EPA issued a proposed rule that would lower the Section 408 tolerance for daminozide on apples from 30 to 20 ppm. 51 Fed. Reg. 12,889 (1986). That rule became effective on January 16, 1987. 52 Fed. Reg. 1,909 (1987). Subsequently, this interim tolerance was extended through January 31, 1989, 52 Fed. Reg. 28,256 (1987), and again through July 31, 1990, 54 Fed. Reg. 6,392 (Feb. 10, 1989).

3. On July 1, 1986, certain of the petitioners filed an administrative petition with EPA seeking the revocation of all tolerances for daminozide previously issued under Sections 408 and 409 of the FDCA and issuance of regulations establishing new tolerances at zero (Pet. App. 20-45). Relying on the same studies that had been the subject of the earlier proceedings under FIFRA, the petition alleged that Sections 408 and 409 obligated the EPA to establish zero tolerances for daminozide applicable to all raw and processed foods.

The Agency responded to the petition in a letter dated January 6, 1987 (Pet. App. 46-65). The letter reviewed at length the regulatory history of daminozide, the EPA's understanding of its mandate under Sections 408 and 409, the scientific evidence available on daminozide's risks, the pesticide's benefits, and the regulatory actions that the EPA was taking to deal with those risks. *Id.* at 47-64. Referring to the fact that the EPA had required Uniroyal to conduct various studies and provide the EPA with the results, the letter concluded (*id.* at 65):

> Until these studies are received, the Agency cannot reach any definitive conclusions about the long-term risks posed by the use of daminozide. Based on available data, however, the Agency has concluded that any risk posed to consumers during the time period required for data generation is small, while the benefits are high for the production of an adequate, wholesome, and economical food supply. Accordingly, the Agency believes that it has acted properly to protect the public health.

4. Petitioners sought judicial review in the court of appeals, arguing that the court had jurisdiction under Section 408(i) of the FDCA, 21 U.S.C. 346a(i), and Section 409(g), 21 U.S.C. 348(g). Pet. App. 10, 12. The court of appeals dismissed for lack of jurisdiction. *Id.* at 1-19.

a. The court held that it had no jurisdiction under Section 409(g) because petitioners had not filed objections to the EPA's denial of their petition in accordance with Section 409(f), and thus were not pursuing an appeal from an order passing on those objections. The court explained that Section 409(g), "[b]y its plain terms, * * * permits judicial review in [the courts of appeals] only of orders issued under subsection (f)," which provides for the filing of objections and the issuance of orders upon those objections. Pet. App. 12. Section 409(g) does not, the court continued, authorize review of "the grant or denial of the petition in the first instance" under subsection (c) or (d) (*ibid.*).

b. The court of appeals also held that it lacked jurisdiction under Section 408(i) of the Act to review the EPA's refusal to initiate a rulemaking to reduce to zero all tolerances for raw agricultural commodities. Rejecting petitioners' argument that the EPA's refusal to commence a rulemaking was an "order" under subsection (e) for which subsection (i) provides review, the court explained that "the plain wording" of subsection (e) "denominates as an 'order' only one act of the Administrator: the publishing of a regulation." The court added that subsection (i) "authorizes review only of *orders,* not of every act by which a petitioner is aggrieved." Pet. App. 13. The court found further support for its position in the legislative history of Section 408, and in the definition of the term "order" in the Administrative Procedure Act, 5 U.S.C. 551(6). Pet. App. 13-14.

c. The court also expressed concern that granting review in this case would encourage parties to circumvent the procedures that precede the issuance of tolerances under the FDCA. Pet. App. 15-17. It noted that petitioners had not taken advantage of opportunities to present their position in administrative proceedings to reduce

tolerances for daminozide that the EPA had conducted shortly after their petition had been acted upon (*id.* at 15-16). Since petitioners had "bypassed the important intermediate step of objecting and requesting a hearing before the Agency," the court added, granting review would require the court "in essence * * * to perform work the Agency, with its expertise, is far better qualified to do." *Id.* at 16. Similarly, the court observed that "the lack of a hearing and fully developed record deprives this court of the full benefit of the Agency's expertise." *Id.* at 17.

Finally, the court distinguished various decisions, applying other statutes, on which petitioners relied. The court observed that cases from other circuits in which decisions not to initiate rulemakings had been reviewed involved statutes that did not "employ analogous language in respect to their grants of jurisdiction to that contained in the FDCA." Pet. App. 17. Similarly, the court distinguished this Court's decision in *Florida Power & Light Co.* v. *Lorion,* 470 U.S. 729 (1985), which held reviewable the denial of a petition challenging a license for a nuclear power plant, on the ground that the statutes in that case were "separate" and "dissimilar." Pet. App. 18. The holding in *Florida Power & Light,* the court of appeals explained, "depended on its lengthy exegesis of those specific statutes; nowhere did the Court intimate that it was ruling as a matter of general administrative procedure." *Ibid.*

ARGUMENT

There is no conflict between the court of appeals' decision and the decisions of this Court or of other courts of appeals. Moreover, to date, decisions addressing the availability of judicial review of denials of requests by interested persons for rulemakings under Sections 408 and 409 of the FDCA have been rare. In these circumstances, review by this Court is not warranted.

Petitioners' principal contention is that the court of appeals' decision conflicts with this Court's decision in *Florida Power & Light* and decisions from the circuits which, citing *Florida Power & Light*, have held that the courts of appeals have jurisdiction to review various agency actions under statutes other than the FDCA. Pet. 8-13. In *Florida Power & Light,* this Court, construing Section 189 of the Atomic Energy Act of 1954, 42 U.S.C. 2239, and the Hobbs Act, 28 U.S.C. 2341 *et seq.*, held that a court of appeals had jurisdiction to review a refusal by the NRC to initiate a proceeding to modify, suspend or revoke a license for a nuclear power plant. However, as the court of appeals observed (Pet. App. 18), *Florida Power & Light* was based on careful analysis of the particular statutes in issue in that case. Though the Court placed substantial weight on policy considerations favoring initial review in the courts of appeals (470 U.S. at 741-743), it did so only after concluding that the statutory language was ambiguous on the point (*id.* at 735-737). The Court emphasized that whether "subject-matter jurisdiction lies initially in the courts of appeals must of course be governed by the intent of Congress and not by any views [the Court] may have about sound policy." *Id.* at 746.

In this case, therefore, it is necessary to focus on the pertinent provisions of the FDCA in order to determine which court, if any, has jurisdiction to review the EPA's refusal to promulgate regulations revoking all tolerances for daminozide. As the court of appeals correctly noted, " 'courts of appeals have only such jurisdiction as Congress has chosen to confer upon them.' " Pet. App. 18 (quoting *Cutler* v. *Hayes,* 818 F.2d 879, 887 n.61 (D.C. Cir. 1987)). Moreover, tolerances established under Sections 408 and 409 of the Act must be analyzed separately. Though petitioners joined requests for action on tolerances established under both provisions in their administrative petition to

the EPA, those Sections set forth somewhat different procedures for rulemakings and judicial review.

1. Section 408(i)(1) grants review, in "a case of actual controversy," over "the validity of any order under subsection (d)(5), (e), or (*l*)." Subsection (e), the only one of these three sections in issue in this case, describes only one type of agency action as an order: When the EPA chooses to promulgate a regulation establishing a tolerance, it is required to do so "by order." Nevertheless, petitioners contend that another action—a decision not to propose a tolerance in response to a request from an "interested person"—also qualifies as an "order." Pet. 10. Though petitioners' contention is not insubstantial, the court of appeals' conclusion that the category of orders under subsection (e) does not include a refusal to propose a regulation under that subsection does not warrant this Court's review in the absence of a conflict among the circuits.

At the outset, there is persuasive support for the court of appeals' interpretation in both the language of the statute and its legislative history. Though the agency has issued regulations that obligate it to explain refusals to propose tolerances in response to requests from interested persons (40 C.F.R. 180.29), the furnishing of those explanations does not transform agency inaction on a request for a rulemaking into the issuance of an "order" within the meaning of the statute. In this respect, the Administrative Procedure Act (APA) is instructive. It draws a distinction between an "order"—"the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing" (5 U.S.C. 551(6))—and a broader category of "agency action"—"the whole or a part of an agency rule, order, license, sanction,

relief, or the equivalent or denial thereof, or failure to act" (5 U.S.C. 551(13)). Though a refusal to initiate a rulemaking may qualify as "agency action"—*i.e.*, the "denial" of a request to propose a regulation or a "failure to act" on such a request—it would not qualify as an "order." Correspondingly, the court of appeals here was justified in concluding that the FDCA should not be interpreted as departing from this familiar usage of the term "order," except to the extent that the statute or its legislative history designates other agency action as an "order."[7]

Indeed, the legislative history demonstrates that Congress did not contemplate that review would be available for an agency action that Section 408 did not designate as an "order." The Senate Committee Report's description of Section 408(i) explained (S. Rep. No. 1635, 83d Cong., 2d Sess. 10 (1954) (emphasis added)):

> This subsection provides for judicial review in the United States courts of appeals of *orders* * * * *estab-*

---

[7] Elsewhere in the FDCA, the term "order" is used to describe an action in various administrative proceedings that triggers another step in the proceeding or judicial review. In addition to Sections 408 and 409, the term "order" is used in this manner in 21 U.S.C. 355 (1982 & Supp. IV 1986) (new drugs); 21 U.S.C. 360b (new animal drugs); and 21 U.S.C. 376 (color additives). It thus appears that Congress used this term in that Act as a means of specifying the particular agency actions that may, by timely request, be made the subject of prescribed administrative or judicial review.

Petitioners argue that, if the denial of their petition with respect to tolerances issued under Section 409 was an "order," that denial with respect to tolerances issued under Section 408 must also be an "order." Pet. 10-11. However, Section 409(c)(1)(B) expressly describes the denial of a petition under that Section as an "order," whereas Section 408(e) does not use that term with respect to a refusal to propose a regulation in response to a request from an interested citizen. Therefore, to the extent it is relevant, the contrast between these provisions supports the court of appeals' conclusion.

> *lishing tolerance or exemption regulations* and of orders * * * with respect to certifications of usefulness. Review is available in any case of "actual controversy" to any person who will be adversely affected by tolerance or exemption regulations or by a certification as to agricultural usefulness.

This description of the jurisdiction being conferred on the courts of appeals obviously does not extend to review of agency determinations not to propose regulations.

To be sure, an interpretation of Section 408(i) that excludes refusals to propose tolerances in response to requests by interested persons may lead to efforts to obtain review in the district courts under the Administrative Procedure Act and 28 U.S.C. 1331. Even if those refusals were held reviewable,[8] however, that would not produce the kind of "implausible results" (470 U.S. at 742) that the Court invoked as support for its conclusion in *Florida Power & Light.*

In *Florida Power & Light,* the respondent proposed an interpretation of the relevant statutes under which the availability of review in the court of appeals would depend on whether a hearing had been held in a licensing proceeding. This position created the risk that the very same order could be reviewed in the district court or the court of appeals depending on whether a party had chosen to request a hearing. See 470 U.S. at 741-742. Moreover, there was a risk of "bifurcation of review"—*i.e.,* review by the district court of ancillary or preliminary orders and by the

---

[8] We do not concede that a mere refusal to issue a proposed rule is reviewable under the APA. Other considerations, such as statutory preclusion of review (5 U.S.C. 701(a)), finality, exhaustion of remedies and other similar doctrines could be relevant. See *Florida Power & Light,* 470 U.S. at 735 n.8. Questions arising under those doctrines are not presented in this Court with respect to Section 408.

court of appeals of the final order in the licensing proceeding. See *id.* at 743. Under the court of appeals' holding in this case, by contrast, the roles of the two courts would be more clearly compartmentalized. If any review were available in the district court of a refusal to propose a tolerance, it would be extremely narrow. Since action by the EPA on a request for issuance of a proposal is discretionary (see Pet. App. 13), review would presumably be limited to the question whether the refusal to act was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. 706(2)(A). Moreover, the appropriate relief for an erroneous refusal by the agency to publish a proposal would be to remand for further proceedings to correct any deficiency in the agency's decisionmaking process and reconsider whether to propose a regulation. A court could not, upon review of a decision not to propose a regulation, grant relief that would bypass the statutory procedures for issuance of a final regulation. If, following a remand, the EPA issued a proposal, subsequent steps of the rulemaking process would be reviewable in the court of appeals under Section 408(i) following issuance of an "order" in the rulemaking. The severe anomalies suggested by petitioners (Pet. 13) therefore would not arise.

As the court of appeals explained, the FDCA is distinguishable from the statutes at issue in *Florida Power & Light,* and the court of appeals' interpretation of Section 408(i) is therefore consistent with this Court's holding and reasoning in that case. Nor is there a conflict between the court of appeals' decision and decisions of other courts of appeals. With one exception, all of the decisions upon which petitioners rely (Pet. 12-13) involved statutes other than the FDCA and language unlike that of Section

408(i).[9] As *Florida Power & Light* makes clear, the question of what agency actions are reviewable in the courts of appeals must be resolved by reference to the particular statute involved, based upon its language and, if pertinent, its legislative history, other sources of Congress's intent with respect to that statute, and considerations of policy. Decisions placing review in the courts of appeals under statutes other than the FDCA thus do not give rise to a conflict of the type that would support review in this Court.

Moreover, cases in which parties have attempted to obtain review of decisions not to propose tolerances under Section 408 have been very rare. In these circumstances,

---

[9] See *Commonwealth Edison Co.* v. *Nuclear Regulatory Comm'n*, 830 F.2d 610, 612-613 (7th Cir. 1987) (Hobbs Act); *Vineland Chemical Co.* v. *EPA*, 810 F.2d 402, 406 (3d Cir. 1987) (Resource Conservation and Recovery Act); *Tennessee* v. *Herrington*, 806 F.2d 642, 647 (6th Cir.), cert. denied, 107 S. Ct. 1604 (1987) (Nuclear Waste Policy Act); *Modine Mfg. Corp.* v. *Kay*, 791 F.2d 267, 269 (3d Cir. 1986) (Clean Water Act); *Public Utility Comm'r* v. *Bonneville Power Admin.*, 767 F.2d 622, 625-626 (9th Cir. 1985) (Pacific Northwest Electric Power Planning and Conservation Act); *Telecommunications Research & Action Center* v. *FCC*, 750 F.2d 70, 75 (D.C. Cir. 1984) (28 U.S.C. 2342(1), 47 U.S.C. 402(a)).

The one exception is *Environmental Defense Fund* v. *HEW*, 428 F.2d 1083 (1970), in which the District of Columbia Circuit did review a refusal by the agency that previously administered Section 408 to act on a petition to reduce the tolerance for DDT in raw foods. However, that decision predated *Florida Power & Light*, and the court nowhere addressed the question whether Section 408(i) gave the court jurisdiction over the case. Moreover, the decision was based on the apparent misconception that EDF's request for promulgation of a regulation was a petition under Section 408(d), a Section limited by its terms to FIFRA registrants. See 428 F.2d at 1090 (requiring publication of that request under subsection (d)). For these reasons, the question presented here has not been definitively resolved for the D.C. Circuit.

we submit, further review of the court of appeals' decision is not warranted in the absence of a conflict among the circuits.[10]

2. The court of appeals correctly held that judicial review is not available under Section 409 of the Act until and unless objections have been filed to a regulation issued under subsections (c) and (d) and the EPA has acted on those objections. Unlike the issue just discussed under Section 408, however, the issue under Section 409 is whether the filing of objections with the agency is an administrative remedy that must be exhausted before review may be sought. Here, the court of appeals, we submit, properly held that petitioners, having failed to take the step required by Section 409(f), could not obtain review of the Agency's refusal to issue or amend regulations applicable to processed foods.

Section 409(g) gives the courts of appeals authority to review "the validity of any order issued under subsection (f) of this section, including any order thereunder with respect to amendment or repeal of a regulation issued under this section." Though the statute does not directly address the question of judicial review of orders issued under subsections (c) and (d)—the types of orders to which objections are to be filed under subsection (f)—any suggestion that such orders are reviewable under the APA would obviously be inconsistent with the procedural scheme established by Section 409. On its face, Section 409 establishes a multi-step procedure that allows for prompt

[10] Moreover, if a court were to disagree with a party's choice of the forum for review, 28 U.S.C. 1631 would allow transfer of the case to the proper court if one were available. This avenue, when it is invoked in a timely fashion, should be sufficient to protect parties against the risk of losing the opportunity to obtain review to which they are otherwise entitled on the basis of a mistaken judgment on the proper forum for review.

promulgation of regulations, followed by an appeal within the agency and only then by judicial review, which is in the court of appeals.

The purpose of this scheme is apparent. It allows the EPA to get a regulation concerning a pesticide in place quickly, thereby giving farmers and ultimately consumers the benefit of safe, new chemicals, while protecting the public against health risks. By means of objections filed in accordance with subsection (f), the Agency is then informed of specific concerns from any of the various persons that may be adversely affected by the regulation or a refusal to issue one. These objections are then the subject of a hearing, if necessary, and are followed by an order, "based upon a fair evaluation of the entire record at such hearing," which includes "a statement setting forth in detail the findings and conclusions upon which the order is based." 21 U.S.C. 348(f)(2). This procedure assures that the Agency, as opposed to the reviewing court, makes the judgments committed by the statute to the EPA's expertise, allows the Agency the first opportunity to address specific concerns with its regulations, and, by virtue of the requirement of detailed findings on a record, facilitates judicial review. To curtail this process by permitting review of orders issued under subsections (c) and (d) would obviously undercut the statutory scheme.

The Senate Committee Report that accompanied Section 409 confirms that parties are required to exhaust their administrative appeals under subsection (f) before seeking judicial review in the courts of appeals. S. Rep. No. 2422, 85th Cong., 2d Sess. 7-8 (1958). After describing the procedures for filing objections and obtaining a hearing, and the reasons for the applicable standard of review, the report states that "[j]udicial review of any order of the Secretary under this legislation may be obtained in the United States court of appeals for the circuit wherein ap-

pellant resides, or has his principal place of business, or in the United States Court of Appeals for the District of Columbia." *Id.* at 8. In conjunction with the language of subsection (g), which limits appeals to orders issued under subsection (f), it is clear that Congress contemplated that only those orders issued upon objections would be reviewable.[11]

There is no basis for petitioners' suggestion (Pet. 11-12, 15-16) that this interpretation of the statute is contrary to the position taken by the Food and Drug Administration or other courts. In *Public Citizen* v. *Bowen,* 833 F.2d 364 (D.C. Cir. 1987), for instance, the FDA made a motion to transfer a premature appeal from a district court to the District of Columbia Circuit. See Pet. App. 66-72. Far from suggesting that review would be available before objections had been filed, the FDA explained that the court of appeals would be required to dismiss the case because "plaintiffs have failed to exhaust their administrative remedies." *Id.* at 72 n.7. Similarly, there are no decisions under Section 409 that remotely suggest that persons filing a so-called "citizens' petition" may bypass administrative procedures set out in the statute that are applicable to all

---

[11] As petitioners note (Pet. 15), the D.C. Circuit has permitted a public interest group to challenge a regulation issued under Section 408(e) without first filing objections in accordance with Section 408(d)(5). *National Coalition Against the Misuse of Pesticides* v. *Thomas,* 809 F.2d 875 (D.C. Cir. 1987) (*NCAMP*). Because *NCAMP* and this case involve separate sections of the FDCA, there is no conflict warranting this Court's review between *NCAMP* and the decision here. We believe, however, that *NCAMP* was wrongly decided, since, without giving adequate attention to the structure of the procedure established by the statute, it undercuts procedures of Section 408 that, like those of Section 409, assure that courts do not displace the EPA in making the judgments required by Section 408(b) (see note 2, *supra*) and facilitate review.

rulemakings under Section 409. See Pet. 12.[12]

Finally, there is no merit to the suggestion that denials of citizen petitions that contain detailed challenges to use of a particular pesticide may be appealed immediately because objections would be a "futile exercise." Pet. 12. All persons who petition for a regulation under Section 409 must file detailed submissions with the agency involved. See 21 U.S.C. 348(d)(1). Notwithstanding the detail the agency receives in the initial submissions, Congress decided that the filing of objections would assist the agency in focusing on matters in dispute and create a record that facilitates judicial review. In this respect, petitions filed by members of the public are entitled to no different treatment than petitions filed by any other type of party. Moreover, there is no basis for assuming in any particular case that objections would serve no useful purpose. In this case, for instance, the dispute between petitioners and the EPA concerns primarily an issue of scientific fact—the reliability of studies suggesting that daminozide creates a risk of cancer. As the court of appeals observed (Pet. App. 16-17), allowing review at this stage would force the court "in essence to perform work that the Agency, with its expertise, is far better qualified to do" and deny the court "the full benefit of the Agency's expertise."

Because petitioners did not file objections under Section 409(f) to the EPA's action on their administrative petition, the court of appeals correctly refused to review the EPA's action with respect to Section 409 tolerances for processed

---

[12] The facts of *Community Nutrition Inst.* v. *Young*, 773 F.2d 1356, 1360 (D.C. Cir. 1985), cert. denied, 475 U.S. 1123 (1986), reflect that a citizen group did file objections before seeking review under Section 409. There is no merit, therefore, to petitioners' suggestion that the need for such objections—which is plain on the face of the statute in any event—was unforeseeable.

foods.[13] There is no conflict between that decision and any decision of this Court or of any other court of appeals. Indeed, this case appears to be the first one in which any court of appeals has specifically addressed the question whether the filing of objections is an administrative remedy whose exhaustion is a prerequisite to judicial review. Further review by this Court of that question is therefore not warranted.

---

[13] As the petition indicates (Pet. 14), the EPA did not publish its response to the administrative petition. However, under the facts of this case, that circumstance does not support review by this Court. At the time that the administrative petition was filed, there were only two Section 409 tolerances for daminozide; these applied to dried prunes and concentrated tomato products. When it responded to petitioners' administrative petition, the EPA advised petitioners that it intended to revoke the tolerance for prunes and reduce the tolerance for tomato products. Pet. App. 63. Thus, the only remaining point in dispute under Section 409 related to tomato products. On March 3, 1987, in accordance with its undertaking in its response to petitioners' administrative petition, the EPA published a proposed regulation that would lower the tolerance for tomato products and on July 22 that regulation because effective. 52 Fed. Reg. 6,348 (1987); 52 Fed. Reg. 27,543 (1987). Though petitioners had a right, if they disputed the tolerance for tomato products as reduced, to file objections and pursue review, they did not follow that course. Under the circumstances of this case, therefore, the EPA's subsequent publication of a regulation in accordance with the decision on the petition was the functional equivalent of publication of the decision. There is no doubt that petitioners had notice of the decision on their administrative petition, were made aware of upcoming action with respect to the tolerance for concentrated tomato products, and chose not to participate in administrative proceedings regarding that tolerance—the only one that remains in issue under Section 409. Finally, in the court of appeals, petitioners did not argue that they had been denied an opportunity to file objections because the decision on the petition had not been published. Instead, they maintained that the objection requirement was totally inapplicable to their administrative petition. See Pet. C.A. Rep. Br. 12-13. Under all of these circumstances, this fact-bound issue does not support review here.

CONCLUSION

The petition for a writ of certiorari should be denied.
Respectfully submitted.

WILLIAM C. BRYSON
Acting Solicitor General
DONALD A. CARR
Acting Assistant Attorney General
ASHLEY DOHERTY
Attorney

MARCH 1989

U.S. GOVERNMENT PRINTING OFFICE: 1989—241 699/00177